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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,850	05/17/2006	Deborah Addison	JJM5024USPCT	8913

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EXAMINER

ROBINSON, JAMES MARSHALL

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,850	Applicant(s) ADDISON ET AL.	
	Examiner James M. Robinson	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6, 7, 8 11, & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 (from which claim 6 depends,) recites the broad recitation "comprises a solid bioabsorbable material", and the claim also recites "consisting of" which is the narrower statement of the range/limitation. This claim is clear and is not indefinite. However, claim 6 further

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attempts to further limit the claimed material using an open-ended transitional phrase "comprises" rendering claim 6 indefinite. Appropriate correction is required.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "said silver salt comprises a salt of Ag+ **with the anionic polymer.**" The combination of salt of Ag+ and an ionic polymer is no longer a "silver salt" thus rendering the claim indefinite.

5. Claim 7 recites the limitation "the composition" in --line 2--. There is insufficient antecedent basis for this limitation in the claim.

6. Regarding claim 8, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Regarding claim 11, the phrase "and/or" renders the claim indefinite because it is unclear what the substrate consists of. Furthermore in the case of "or," the recitation fails to further limit the subject matter.

8. Regarding claim 11, the phrase "herein defined" renders the claim indefinite because it is unclear as to where the claimed subject matter is defined.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1- 6 & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lilienfeld (US 2296856).

Regarding claim 1, Lilienfeld discloses a wound dressing material (pg. 5 col. 1, line 40) comprising a polymeric substrate (pg. 1 col. 1, line 5), a silver salt (pg. 12 col. 1, lines 26-34), and a dyestuff (pg. 7 col. 1, line 3). Regarding “dyestuff to photostabilize the silver salt,” the limitation has been treated as an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the limitation has not been positively claimed, the dyestuff of the Lilienfeld patent is capable of performing the recited function.

Regarding claims 2-5, Lilienfeld discloses a wound dressing material wherein the substrate comprises a solid biabsorbable material such as cellulose (and derivatives

thereof) (pg. 1 col. 1, line 5) in woven form (pg. 6 col. 2, line 72). The cellulose derivatives containing in their molecule a hydroxy-acid is a form of oxidized cellulose.

Regarding claims 6, Lilienfeld discloses a wound dressing material wherein the polymeric substrate comprises an anionic polymer (derivatized cellulose), and a silver salt comprises a salt of Ag⁺ with the anionic polymer (pg. 12 col. 1, lines 26-34).

Regarding claims 13, there is no positive claimed structure but rather a property met by a test is claimed. The properties of the wound dressing material disclosed in Lilienfeld are the same as those claimed by applicant; therefore Lilienfeld's material would be capable of, if subjected to the DPPH test, exhibiting essentially an antioxidant activity of at least about 15%. Therefore, the limitations of the claim are met.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilienfeld (US 2296856) in view of Feldstein et al. (US 2005/0113510). Lilienfeld substantially discloses the invention as claimed, the specific limitations in claims 7-12, see rejections to claims 1-6 above, however, regarding claim 7, Lilienfeld is silent to a wound dressing material wherein a composition of about 0.01wt.% to about 5wt.% of silver, based on the dry weight of the composition.

Feldstein discloses a wound dressing material wherein the composition comprises from about 0.01wt.% to about 5wt.% of silver, based on the dry weight of the composition [0229].

To provide the wound dressing material of Lilienfeld with a composition comprising from about 0.01wt.% to about 5wt.% of silver, based on the dry weight of the composition, it would have been obvious to one of ordinary skill in the art at the time of the invention, in view of the teachings of Feldstein, in order to enhance the oxidative-reductive powers of silver salts an effective composition range must be sought to light stabilize the wound dressing in order to enhance its anti-microbial effect. Further, it would be obvious to one of ordinary skill in the art to have chosen an optimal concentration by weight of silver, within the claimed range, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 8-9, Lilienfeld fails to explicitly disclose the dyestuff is an antioxidant dyestuff.

However, Feldstein discloses a wound dressing material comprising an antioxidant dyestuff ([134]-[138]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide the wound dressing material of Lilienfeld with a dyestuff that is of the antioxidant type in view of the teachings of Feldstein. Doing so would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that an

antioxidant type dyestuff is conventional in the art, for example, to light stabilize the wound dressing to enhance its anti-microbial effect since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 10, Lilienfeld fails to explicitly disclose the dyestuff is present in an amount of from about 0.2 to about 2wt.% based on the dry weight of the material.

However, Feldstein discloses a wound dressing material including a dyestuff is present in an amount of from about 0.2 to about 2wt.% based on the dry weight of the material [0138].

To provide the wound dressing material of Lilienfeld with a composition comprising from about 0.2 to about 2wt.% based on the dry weight of the material of dyestuff, based on the dry weight of the composition, it would have been obvious to one of ordinary skill in the art at the time of the invention, in view of the teachings of Feldstein, in order to optimize the anti-microbial effect of the dressing material. Further, it would be obvious to one of ordinary skill in the art to have chosen an optimal concentration by weight of dyestuff, within the claimed range, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 11, Lilienfeld discloses a wound dressing material a wherein the polymeric substrate consists essentially of a mixture of oxidized cellulose derivatives (pg. 2, col. 2, lines 13-16).

Lilienfeld fails to disclose the polymeric composition consists essentially a mixture of an oxidized cellulose with a collagen and/or a chitosan.

However, Feldstein discloses a wound dressing material wherein the polymeric substrate consists essentially of a mixture of an oxidized cellulose with a collagen and/or a chitosan [0065].

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the polymeric composition of Lilienfeld's wound dressing as a mixed composition of a collagen and/or a chitosan. One skilled in the art would have recognized that the hybridized composition would be effective, for example, to light stabilize the wound dressing to enhance its anti-microbial effect since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. .

Regarding claims 12, Lilienfeld fails to disclose the use of packaging. However, Feldstein discloses a wound dressing material wherein the material is packaged in a container [0168]. Further, is well known and conventional in the art of wound dressings to package wound dressing and keep it sterile prior to use and ensure that the dressing will prevent contamination of the wound at the site of bandage application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to package the wound dressing of Lilienfeld with the microorganism impermeable container of Feldstein in order to maintain dressing sterility.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Karandikar (US 20070003603), Kitahata (US 20070166438), Tessier (US 20060141015), and Canada (US 20050037680).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 7:30 AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

May 22, 2008

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/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772